K003899

Section E – 510(k) Summary

MAR 15 2001

MRI Devices Corporation
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Waukesha, Wisconsin 53186
Phone (262) 524 - 1402
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December 12, 2000

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Company Name:	MRI Devices Corporation 1515 Paramount Drive Waukesha, WI 53186
Registration Number:	2184005
Contact Person:	William Dinehart
Telephone Number:	262-524-1402
Prepared:	December 12, 2000
Device Name:	IFIS-SA Integrated Functional Imaging System
Classification Name:	Magnetic Resonance Diagnostic Device
Classification:	Class II (LNH)
Common Name:	Workstation
Predicate Devices:	Philips Easy Vision Family Workstation Option BOLD Analysis Package, K990329 Functional MRI Package for Magnetom Vision MR K984221 M.R. VISION 2000 ULTRA AUDIO VISUAL SYSTEM K994351 Silent Scan Hearing Protection and Communication Sys. K921891

Device Description:

The IFIS-SA is a stand-alone experiment presentation and postprocessing workstation. The IFIS-SA package supports the visualization and analysis of MRI studies based on Blood Oxygen Level Dependent (BOLD) contrast. The image contrast differs between scans as a result of the variation of blood oxygenation through task performance by the subject (e.g., finger tapping). BOLD data can be processed with the IFIS-SA to provide analysis based on standard statistical methods.

Intended Use:

The device, IFIS-SA, described in this submission, provides dedicated visualization and analysis of MRI studies based on Blood Oxygen Level Dependent (BOLD) contrast which are useful for quantifying and visualizing small susceptibility changes in the human brain, created by the execution of specific tasks. These susceptibility images can be overlaid on the anatomical images to optimize the presentation of information to support the diagnostic process. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

The IFIS-SA may also be used as a patient entertainment system, via its ability to deliver high quality audio and video to the patient.

Safety Information:

No new safety hazards are introduced by the use of the IFIS-SA.

Thomas Schubert, President
December 12, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Thomas Schubert
President
MRI Devices Corp.
1515 Paramount Drive
WAUKESHA WI 53186

Re: K003899
Model IFIS-SA Integrated Functional Image System
Dated: December 12, 2000
Received: December 18, 2000
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNH

Dear Mr. Schubert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section C – Statement of Indications for Use:

Applicant: MRI Devices Corporation
510(k) number (if known): K00 3899
Device Name: IFIS-SA Integrated Functional Imaging System

Indications for use:

To be used in conjunction with a Magnetic Resonance Scanner to analyze data acquired using Blood Oxygen Level Dependent (BOLD) contrast techniques, such analysis that can be interpreted by a trained physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003899

Prescription Use ✓ or Over-The-Counter Use ___

(Per 21 CFR 801.109)